



**FORMATION DISCLOSURE CITATION
IN AN APPLICATION**
(Use several sheets if necessary)

PTO Form 1449

Atty Docket No. 119742-004	Application No. 10/510,411
Applicant Habib Zaghouani, Ph.D.	Date Submitted August 5, 2008
Filing Date September 12, 2005	Group 1644

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner's Initials	OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)
	Alleva, D.G., A. Gaur, L. Jin, D. Wegmann, P.A. Gottlieb, A. Pahuja, E.B. Johnson, T. Mothermal, A. Putnam, P.D. Crowe, N. Ling, S.A. Boehme, and P.J. Conlon. (2002). Immunological characterization and therapeutic activity of an altered-peptide ligand, NBI6024, based on the immunodominant type 1 diabetes autoantigen insulin 13-chain (9-23) peptide. <i>Diabetes</i> . 51: 2126-2134.

Examiner: _____ **Date Considered:** _____

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Atty Docket No. 119742-004	Application No. 10/510,411
		Applicant Habib Zaghouani, Ph.D.	Date Submitted August 5, 2008
		Filing Date September 12, 2005	Group 1644
PTO Form 1449			

Examiner's Initials	OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)
	Andre, I., A. Gonzalez, B. Wang, J. Katz, C. Benoist, and D. Mathis. 1996. Checkpoints in the progression of autoimmune disease: lessons from diabetes models. <i>Proc. Natl. Acad. Sci. USA.</i> 93:2260-2263.
	Asseman, C., S. Mauze, M. W. Leach, R. L. Coffman, and F. Powrie. 1999. An essential role for IL-10 in the function of regulatory T cells that inhibit intestinal inflammation. <i>J. Exp. Med.</i> 190:995-1004.
	Bach, J.F. 1994. Insulin-dependent diabetes mellitus as an autoimmune disease. <i>Endroc. Rev.</i> 15:516-542.
	Balasa, B., and N. Sarvetnick. 1996. The paradoxical effects of interleukin 10 in the immunoregulation of autoimmune diabetes. <i>Autoimmun.</i> 9:283-286.
	Barrat, F.J., D.J. Cua, A. Boonstra, D.F. Richards, C. Crain, H.F. Savelkoul, R. de WaalMalefyt, R.L. Coffman, C.M. Hawrylowicz, and A. O'Garra. 2002. <i>In vitro</i> generation of interleukin 10-producing regulatory CD4 ⁺ T cells is induced by immunosuppressive drugs and inhibited by T helper type 1 (Th1)- and Th2-inducing cytokines. <i>J Exp. Med.</i> 195:603- 616.
	Bonifacio, E., M. Atkinson, G. Eisenbarth, D. Serreze, T.W. Kay, E. Lee-Chan, and B. Singh. 2001. International workshop on lessons from animal models for human type 1 diabetes: identification of insulin but not glutamic acid decarboxylase or IA-2 as specific autoantigens of humoral autoimmunity in nonobese diabetic mice. <i>Diabetes.</i> 50:2451-2458.
	Bot, A., D. Smith, S. Bot, A. Hughes, T. Wolfe, L. Wang, C. Woods, and M. von Herrath. 2001. Plasmid vaccination with insulin B chain prevents autoimmune diabetes in nonobese diabetic mice. <i>J. Immunol.</i> 176: 2950-2955.
	Brumeau, T.D., W.J. Swiggard, R.M. Steinman, C.A. Bona, and H. Zaghouani. 1993. Efficient loading of identical viral peptide onto class II molecules by antigenized immunoglobulin and influenza virus. <i>J. Exp. Med.</i> 178:1795-1799.
	Bu, Ding Fang et al., "Two Human Glutamate ..." (1992)
	Buschard, K., T. Bock, C.R. Pederson, S.V. Hansen, K. Aaen, M. Jorgenson, M.W. Hansen, T.W. Kjaer, I. Hageman, and K. Josefsen. 2000. Neonatal treatment with beta-cell stimulatory agents reduces the incidence of diabetes in BB rats. <i>Int. Exp. Diabetes Res.</i> 1:1- 8.
	Castano, L., and G.S. Eisenbarth. 1990. Type-1 diabetes: a chronic autoimmune disease of human, mouse, and rat. <i>Ann Rev. Immunol.</i> 8:647-680.

incomp.
cite

Examiner:	Date Considered:
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Atty Docket No. 119742-004	Application No. 10/510,411
		Applicant Habib Zaghouani, Ph.D.	Date Submitted August 5, 2008
		Filing Date September 12, 2005	Group 1644
PTO Form 1449			

Examiner's Initials	OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)		
	Christen, U., T. Wolfe, U. Mahrle, A.C. Hughes, E. Rodrigo, E.A. Green, R.A. Flavell, and M.G. von Herrath. 2001. A dual role for TNF-a in type I diabetes: islet-specific expression abrogates the ongoing autoimmune process when induced late but not early during pathogenesis. <i>J. Immunol.</i> 166:7023-7032.		
	Christian, C.L. 1960. Studies on aggregated gamma-globulin I & II. <i>J. Immunol.</i> 84:112- 121.		
	Daniel, D., and D.R. Wegmann. 1996. Protection of nonobese diabetic mice from diabetes by intranasal or subcutaneous administration of insulin peptide B (9-23). <i>Proc. Natl. Acad. Sci. USA.</i> 93:956-960.		
	Delovitch, T., and B. Singh. 1997. The nonobese diabetic mouse as a model of autoimmune diabetes: immune dysregulation gets the NOD. <i>Immunity.</i> 7:727-738.		
	Dotta, Francesco, Marcello Previti, Marguerite Neerman-Arbez, Sabrina Dionisi, Domenico Cucinotta, Luisa Lenti, Umberto DiMario, The GM2-1 Ganglioside Islet Autoantigen in Insulin-Dependent Diabetes Mellitus is Expressed in Secretory Granaules and is Not β -Cell Specific, <i>Endocrinology</i> , 139(1):316-319, 1998.		
	Faveeuw, C., M.C. Gagnerault, and F. Lepault. 1995. Isolation of leukocytes infiltrating the islets of Langerhans of diabetes-prone mice for flow cytometric analysis. <i>J. Immunol. Methods.</i> 187:163-169.		
	Gottlieb, P.A., and G.S. Eisenbarth. 2002. Insulin-specific tolerance in diabetes. <i>Clin. Immunol.</i> 102:2-11.		
	Groux, H., A. O'Garra, M. Bigler, M. Rouleau, J. de Vries, and M.-G. Roncarolo. 1997. Generation of a novel regulatory CD4+ T-cell population, which inhibits antigen-specific T-cell responses. <i>Nature.</i> 389:737-742.		
	Heath, V.L., P. Hutchings, D.J. Fowell, A. Cooke, and D. Mason. 1999. Peptides derived from murine insulin are diabetogenic in both rats and mice, but the disease-inducing epitopes are different: evidence against a common environmental cross-reactivity in the pathogenicity of type I diabetes. <i>Diabetes.</i> 48:2157-2165.		
	Honeyman, Margo C, Natalie L. Stone, and Leonard C. Harrison, T-Cell Epitopes in Type 1 Diabetes Autoantigen Tyrosin Phosphatase LA-2: Potential for Mimicry with Rotavirus and Other Environmental Agents, <i>Molecular Medicine</i> , 4:231-239, 1998.		
	Jun, H.S., Y.H. Chung, J. Han, A. Kim, S.S. Yoo, R.S. Sherwin, and Yoon, J.W. (2002). H.S. Jun et al.: Prevention of autoimmune diabetes by GAD imunogene therapy. <i>Diabetologia.</i> 45:668-676.		

Examiner:	Date Considered:
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Atty Docket No. 119742-004	Application No. 10/510,411
		Applicant Habib Zaghouani, Ph.D.	Date Submitted August 5, 2008
PTO Form 1449		Filing Date September 12, 2005	Group 1644

Examiner's Initials	OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)
	Latek, R.R., A. Sufi, S.J. Petzold, C.A. Nelson, O. Kanagawa, E.R. Unanue, and D.H. Fremont. 2000. Structural basis of peptide binding and presentation by the type 1 diabetes-associated MHC class II molecule of NOD mice. <i>Immunity</i> . 12:699-710.
	Lee, M.-S., R. Mueller, L. Wicker, L.B. Peterson, and N. Sarvetnick. 1996. IL-10 is necessary and sufficient for autoimmune diabetes in conjunction with NOD MHC homozygosity. <i>J. Exp. Med.</i> 183:2663-2668.
	Legge, K.L., B. Min, N.T. Potter, and H. Zaghouani. 1997. Presentation of a T cell receptor antagonist peptide by immunoglobulins ablates activation of T cells by a synthetic peptide or proteins requiring endocytic processing. <i>Exp. Med.</i> 185:1043-1053.
	Legge, K.L., R.K. Gregg, R. Maldonado-Lopez, L. Li, J.C. Caprio, M. Moser, and H. Zaghouani. 2002. On the role of dendritic cells in peripheral T cell tolerance and modulation of autoimmunity. <i>Exp. Med.</i> 196:217-227.
	Liblau, R.S., S.M. Singer, and H.O. McDevitt. 1995. Th1 and Th2 CD4 ⁺ T cells in the pathogenesis of organ-specific autoimmune diseases. <i>Immunol. Today</i> . 16:34-37.
	Liu, C. Detection of Glutamic Acid Decarboxylase-Activated T cells with I-Ag7 Tetramers. <i>PNAS</i> . 97(26): 14596-14601, 2000.
	Makino, S., K. Kunimoto, Y. Muraoka, Y. Mizushima, K. Katagiri, and Y. Tochino. 1980. Breeding of a non-obese, diabetic strain of mice. <i>Jikken Dobutsu</i> . 29:1-13.
	Min, B., K.L. Legge, C. Pack, and H. Zaghouani. 1998. Neonatal exposure to a selfpeptide-immunoglobulin chimera circumvents the use of adjuvant and confers resistance to autoimmune disease by a novel mechanism involving interleukin 4 lymph node deviation and interferon γ -mediated splenic anergy. <i>J. Exp. Med.</i> 188:2007-2017.
	Moritani, M., K. Yoshimoto, S. Ii, M. Kondo, H. Iwahana, T. Yamaoka, T. Sano, N. Nakano, H. Kikutani, and M. Itakura. Prevention of adoptively transferred diabetes in nonobese diabetic mice with IL-10-transduced islet-specific Th1 lymphocytes. <i>J. Clin. Invest.</i> 98:1851-1859.
	Pennline, K.J., E. Roque-Gaffney, and M. Monahan. 1994. Recombinant human IL-10 prevents the onset of diabetes in the nonobese diabetic mouse. <i>Clin. Immunol. Immunopathol.</i> 71:169-175.
	Phillips, J.M., N.M. Parish, M. Drage, and A. Cooke. 2001. Cutting edge: interactions through the IL-10 receptor regulate autoimmune diabetes. <i>J. Immunol.</i> 167:6087-6091.

Examiner:	Date Considered:
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Atty Docket No. 119742-004	Application No. 10/510,411
		Applicant Habib Zaghouani, Ph.D.	Date Submitted August 5, 2008
		Filing Date September 12, 2005	Group 1644
PTO Form 1449			

Examiner's Initials	OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)
	Pietropaolo, Massimo, Luis Castano, Sunanda Babu, Roland Buelow, Yu-Ling S. Kuo, Stephan Martin, Andrea Martin, Alvin C. Powers, Michal Prochazka, Jurgen Nagert, Edward H. Leiter, and George S. Eisenbarth, Islet Cell Autoantigen 69 kD (ICA69): Molecular Cloning and Characterization of a Novel Diabetes-Associated Autoantigen, <i>J. Clin. Invest.</i> , 92:359-371, July 1993.
	Quintana, F.J., A. Rotem, P. Carmi, and I.R. Cohen. 2000. Vaccination with empty plasmid DNA or CpG oligonucleotide inhibits diabetes in nonobese diabetic mice: modulation of spontaneous 60-kDa heat shock protein autoimmunity. <i>J. Immunol.</i> 16:148- 155.
	Roep, Bart O, Perspectives in Diabetes: T-Cell Responses to Autoantigens in IDDM: The Search for the Holy Grail. <i>Diabetes</i> , 45:1147-1156, September 1996.
	Romani, N., N. Bhardwaj, M. Pope, F. Koch, W.J. Swigard, U.O. Doherty, M.D. Witmer-Pack, L. Hoffman, G. Schuler, K. Inaba, and R.M. Steinman. 1996. Dendritic cells. In Weirs Handbook of Experimental Immunology. L.A. Herzenberg, D. Weir, and C. Blackwell, editors. Blackwell Science, Cambridge. 156.1-156.14.
	Roncarolo, M.G., R. Bacchetta, C. Bordignon, S. Narula, and M.K. Levings. 2001. Type 1 T regulatory cells. <i>Immunol. Rev.</i> 182:68-79.
	Rosenqvist, E., T. Jossang, and J. Feder. 1987. Thermal properties of human IgG. <i>Mol. Immunol.</i> 24:495-501.
	Sarvetnick, N., J. Shizuru, D. Liggitt, L. Martin, B. McIntyre, A. Gregory, T. Parslow, and T.A. Stewart. 1990. Loss of pancreatic islet tolerance induced by 13-cell expression of interferon- γ . <i>Nature</i> . 346:844-847.
	Serze, D.V., H.D. Chapman, C.M. Post, E.A. Johnson, W.L. Suarez-Pinzon, and A. Rabinovitch. 2001. Th1 to Th2 cytokine shifts in nonobese diabetic mice: sometimes an outcome, rather than the cause of diabetes resistance elicited by immunostimulation. <i>J. Immunol.</i> 166:1352-1359.
	Shevach, E. M. 2000. Regulatory T cell in autoimmunity. <i>Ann. Rev. Immunol.</i> 18: 423-450.
	Song, H.Y., M.M. Abad, C.P. Mahoney, and R.C. McEnvoy. 1999. Human insulin B chain but not A chain decreases the rate of diabetes in BB rats. <i>Diabetes Res. Clin. Pract.</i> 46:109-114.
	Tisch, R., and H.O. McDevitt. 1996. Insulin dependent diabetes mellitus. <i>Cell</i> . 85:291-297.

Examiner:	Date Considered:
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Atty Docket No. 119742-004	Application No. 10/510,411
		Applicant Habib Zaghouani, Ph.D.	Date Submitted August 5, 2008
		Filing Date September 12, 2005	Group 1644
PTO Form 1449			

Examiner's Initials	OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)		
	Wang, B., I. Andre, A. Gonzalez, J. Katz, M. Aguet, C. Benoist, and D. Mathis. 1997. Interferon- γ impacts at multiple points during the progression of autoimmune diabetes. <i>Proc. Natl. Acad. Sci. USA.</i> 94:13844-13849.		
	Wegmann, D.R., M. Norbury-Glaser, and D. Daniel. 1994. Insulin-specific T cells are a predominant component of islet infiltrates in pre-diabetic NOD mice. <i>Eur. J. Immunol.</i> 24:1853-1857.		
	Wogensen, L., M.-S. Lee, and N. Sarvetnick. 1994. Production of interleukin 10 by islet cells accelerates immune-mediated destruction of β cells in nonobese diabetic mice. <i>Exp. Med.</i> 179:1379-1384.		
	Yang, Z., M. Chen, R. Wu, L.B. Fialkow, J.S. Bromber, M. McDuffie, A. Naji, and J. Nadler. 2002. Suppression of autoimmune diabetes by viral IL-10 gene transfer. <i>J. Immunol.</i> 168:6479-6485.		
	Yu, L., D.T. Robles, N. Abiru, P. Kaur, M. Rewers, K. Kelemen, and G.S. Eisenbarth. 2000. Early expression of antiinsulin autoantibodies of humans and the NOD mouse: evidence for early determination of subsequent diabetes. <i>Proc. Natl. Acad. Sci. USA.</i> 97:1701-1706.		
	Zaghouani, H., R. Steinman, R. Nonacs, H. Shah, W. Gerhard, and C. Bona. 1993. Presentation of a viral T cell epitope expressed in the CDR3 region of a self immunoglobulin molecule. <i>Science.</i> 259:224-227.		
	Zheng, X., A. Steele, W. Hancock, A.C. Stevens, P.W. Nickerson, P. Roy-Chaudhury, Y. Tian, and T.B. Strom. 1997. A noncytolytic IL-10/Fc fusion protein prevents diabetes, blocks autoimmunity, and promotes suppressor phenomena in NOD mice. <i>J. Immunol.</i> 158:4507-4513.		

Examiner:	/Gerald Ewoldt/	Date Considered:	10/27/2008
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./